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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,340	HUANG, CHIN-SHIOU	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,46-54,56 and 57* is/are pending in the application.

4a) Of the above claim(s) *9,10,26,46-54,56 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 11-25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/10/04;3/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on March 13, 2006.

Status of the Claims

2. Claims 1-27, 46-54, 56 and 57 are currently pending.

3. Applicant's response to the Restriction and/or Election of Species requirements is acknowledged (Applicant elected ***with traverse*** Group I, claims 1-27) and claims 46-54, 56 and 57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim (see below i.e., ***Response to Restriction and/or Election of Species***).

4. Please note: Applicant's elected species (Subgroup 1 = acrylamide hydrogel; Subgroup 2 = peptide; Subgroup 3 = polypeptide; Subgroup 4 = two-dimensional array; Subgroup 5 = oriented imprint cavities) was found in the art. See MPEP § 803.02 (emphasis added):

> On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. ***The prior art search, however, will not be extended unnecessarily to cover all nonelected species.*** Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be

denied entry.

5. Claims 9, 10 and 26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species. Applicants indicated that all claims read on the elected species (e.g., see 3/13/06 Response, page 9, last paragraph), but this statement is false. Applicants elected a "peptide" template molecule, not an "oligosaccharide" or "oligonucleotide" template molecule. Likewise, claim 26 is also withdrawn. A "three-dimensional array" does not read on Applicants' elected "two dimensional" array. The fact that the one, two and three-dimensional arrays disclosed in claims 24-26 are all "arrays" is not material because the species election required the election of a specific array, not a genus or subgenus of arrays (see also Response to Restriction and/or Election of Species below).

6. Therefore, claims 1-8, 11-25 and 27 are examined on the merits in this action.

Response to Restriction and/or Election of Species

7. Applicant's election of Group I (claims 1-27) **with traverse** is acknowledged.

8. The traversal is on the following grounds:

[1] Applicants argue, "Group I is drawn to a subcombination of the elements of claims 46-54, 56 and 57 of Group II" (e.g., see 3/13/06 Response, page 7, last paragraph).

[2] Applicants argue, "... claims 46-54 of Group II recite the surface imprint composition of claim 1 and cannot be practiced by another materially different product, other than the surface imprint composition of claim 1. Furthermore, claims 46-54 of Group II refer to the same subject

matter of the surface imprint composition of claim 1" (e.g., 3/13/06 Response, paragraph bridging page 8).

This is not found persuasive for the following reasons:

[1] The Examiner respectfully disagrees. Groups I and II are related as product and process of use as set forth in the 2/8/06 Restriction requirement (e.g., see page 2, paragraph 3 and as outlined in MPEP § 806.05(h)). For example, MPEP § 806.05(a) defines a "subcombination" as part of a combination (i.e., an element). However, Group II does not represent an "element" of Group I. Rather, Group II represents a method and, as a result, is drawn to more than any particular element of the composition disclosed in Group I.

[2] The Examiner respectfully disagrees. The method of Group II can be practiced with the molecular imprint compositions disclosed by Arnold et al. (e.g., see 35 U.S.C. 102(b) rejection below) and, as a result, can be used with a materially different product. In addition, MPEP § 806.05(h) states that the inventions can be shown to be distinct if "either" (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product." Here, the product as claimed can also be used in a materially different process of using that product. For example, the product can be used in catalysis (e.g., see specification, page 1, line 31), which does not require "capturing" a molecule because the products in an enzymatic reaction are released during catalysis. Furthermore, the claimed surface imprint composition could be used to fabricate elastomeric stamps or chips by providing "protected" areas for etching (e.g., see Zhao et al., page 1070, figure 1; see also Zhao et al. rejection under 35 U.S.C. 102(b) below; see also Hua et al., "Polymer Imprint Lithography with Molecular-Scale Resolution"

Nano Letters, **2004**, *4(12)*, 2467-2471, especially figures 1 and 2), which does not involve "capturing" a molecule. However, the Examiner notes that rejoinder is available in accordance with MPEP § 821.04 (e.g., see 2/8/06 Restriction requirement, page 7, paragraph 17).

9. Applicant's election of species with traverse is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement (with regard to Subgroups 1 and 3-5), the election of species has also been treated as an election without traverse (MPEP § 818.03(a) and/ or 37 CFR 1.111(b)). With regard to subgroup 2, Applicants "further" traverse on the ground that the species "was not recited in the claims" and, presumably as a result, cannot be properly restricted (e.g., see 3/13/06 Response, page 10, paragraph 1). The Examiner respectfully disagrees. MPEP § 808.01(a) permits restriction even when a species is not explicitly recited in a claim (e.g., see MPEP §808.01(a), "In all applications in which no species claims are present and a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required, a requirement for an election of species should be made prior to a search of the generic claim").

10. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

11. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98 (b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be

incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on the form PTO-892, they have not been considered.

12. The references listed on applicant's PTO-1449 form have been considered by the Examiner. A copy of the form is attached to this Office Action (e.g., 5/10/04; 3/13/06).

Specification

13. The specification is objected to over several occurrences of "Serial No._____" (e.g., page 3, lines 12 and 32). Applicant must amend the specification to provide the required serial number(s) at all appropriate locations.

14. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 1-8, 11-25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For ***claims 1 and 27***, the terms "substantial" as used therein is a relative term that

renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here, the specification provides no standard for distinguishing matrix materials that contains a "substantial" fraction of imprint cavities localized at or near the surface from those that do not. For example, Applicants state, "Compared to conventional imprints, the density of cavities located at the surface of the surface imprints of the invention can also be from 20% to 200% greater, from 30% to 300% greater, from 40% to 400% greater, more than 100% greater, more than 200% greater, more than 300% greater, or even more than 400% greater." (e.g., see specification, page 11, last full paragraph). However, this discussion sheds no light on what constitutes a "substantial" fraction because Applicants fail to specify the prior art that is being relied on. That is, unless the number of imprints that reside on or near the surface of a given "conventional" imprint is known, a person of skill in the art cannot calculate what would be "20% to 200% greater" that this amount (i.e., 20% greater than an unknown is still an unknown). In addition, if a given "conventional" imprint has no imprints on or near the surface then Applicants' "substantial" limitation would fail to further limit the claim because 20% more than 0 is still zero.

Furthermore, Applicants define the "cavities" as being at OR "near" the surface wherein the word "near" is a relative term, which renders the claim indefinite and/or unclear. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also MPEP § 2173.05(b). Thus,

the metes and bounds of the claimed invention cannot be determined. Therefore, claims 1, 27 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

B. For ***claims 4 and 5***, the term "heat sensitive " is a relative term that renders the claim indefinite. The term "heat sensitive" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here, the specification lists various heat sensitive compounds such as hydrogels (e.g., see Summary of Invention), but fails to provide a definition that would otherwise allow the metes and bounds of the term to be determined. Therefore, claims 4 and 5 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

C. For ***claim 6***, the phrase "wherein the template molecule corresponds to a portion of a macromolecule of interest" is vague and indefinite. The term "corresponds" in that phrase does not define any meaningful relationship between the template molecule and the portion of the macromolecule of interest with any reasonable degree of precision and particularity. Specifically, the term in question does not serve to describe in what way, or to what extent, the template molecule is "similar" to the portion of the macromolecule of interest. Furthermore, Appellant's specification is of little assistance in this regard. For example, the specification uses the word "corresponds" to describe "shape" (e.g., see specification, Field of Invention, "Surface imprints comprise cavities that correspond in shape to the shape of a template molecule"), "orientation" (e.g., see specification, page 2, lines 12-13, "... the corresponding molecular imprint cavities are also randomly oriented"), "size" (e.g., see specification, page 3, paragraph 2 "In addition,

the template molecule can correspond to a portion of a larger molecule"), the "location" of a reference application (e.g., see specification, page 3, paragraph 2 "Template molecules that correspond to portions of macromolecules are described in detail in copending application Ser. No. ..."), etc. Consequently, the specification does not define the intended metes and bounds of the word "corresponds" with any degree of particularity or provide any consistent usage for the term that would allow a person of skill in the art to infer such a definition. Therefore, claim 6 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 1-8, 11-25 and 27 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 USC 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a written description rejection.

Applicants' claims are directed to a broad genus of surface imprint compositions comprising a matrix material defining imprint cavities of a template molecule wherein a

substantial fraction of the imprint cavities are localized near the surface of the matrix (e.g., see claims 1 and 27). Thus, Applicants' claims encompass virtually an infinite number of compositions because no structural limitations are set forth for the matrix material, cavity or template (e.g., see specification, section 5.4, "Virtually any type of macromolecule can be captured, isolated, detected, analyzed and/or quantified using the methods and compositions of the invention"). That is, the specification and claims do not place any limit on the number of atoms, the types of atoms, or the manner in which said atoms might be connected to form claimed composition. Furthermore, the dependent claims likewise fail to limit one or more of these claimed elements. For example, dependent claim 2 fails to limit the target and the cavity and still reads on virtually an infinite number of polymer matrices.

In contrast, Applicants' specification disclose only one working example of a polyacrylamide composition that is used to define cavities for a cytochrome c protein target (e.g., see Examples 1 and 4 wherein the LKKATNE of the c-terminus is used to prepare the imprint; see also Examples 2, 3, 5, and 6 outlying various methods of use for this system). Although the specification sets forth a laundry list of other species (e.g., see claim 3 disclosing a laundry list or polymer materials), there is no evidence that any of these materials was actually made or tested.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed invention (e.g., see *In re Edwards*, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978); see also see also *Vas-Cath Inc. v. Mahurkar*, 19

USPQ2d 1111 (CAFC 1991)). The "written description" requirement may be satisfied by using "such descriptive means as words, structures, figures, diagrams formulas, etc., that fully set forth the claimed invention" (e.g., see *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966). In addition, when there is *substantial variation within the genus*, one must describe a sufficient variety of species to reflect the variation within the genus (e.g., see MPEP § 2163.05). Here, Applicant's one example (e.g., polyacrylamide imprinted with a cytochrome c peptide target) does not adequately represent the variation within the genus because Applicants are claiming virtually an infinite number of compositions that do not possess any common structural attributes. For example, Cormack et al. state, "much more research is also required to extend the size range of templates that can be routinely imprinted. At present only small molecules ... can be imprinted with any great confidence" (e.g., see Cormack et al., page 122, column 2, paragraph 3) (3/13/06 IDS, C1). Thus, a person of skill in the art would not conclude that Applicants were in possession of surface imprint compositions containing cavities for larger template molecules, especially in light of the fact that their only disclosed working example is drawn to a small peptide (e.g., LKKATNE). Furthermore, Cormack et al. state, "a much better understanding of the imprinting process at the molecular level is necessary ... [to develop] new functional monomers, cross-linkers and polymerization procedures" (e.g., see Cormack et al., page 122, column 1, paragraph 1) and, as a result, a person of skill in the art would not conclude that Applicants were in possession of every conceivable monomer, cross-linker and polymerization process that would otherwise be necessary to produce the infinite number of currently claimed compositions.

The CAFC has also stated that a "written description on an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." (e.g., see *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)). Here, Applicants have failed to provide a definition, structure, formula or chemical name for any of the compositions. For example, claim 1 sets forth the composition is purely functional terms (e.g., matrix material that has the ability to define a cavity of a molecule that hast the ability to function as a template).

Thus, applicants have not demonstrated in "full, clear, concise, and exact terms" that they are in possession of the claimed invention. Furthermore, the general knowledge and level of skill in the art do not supplement the omitted description because no known structure/function relationship and/or chemical properties exists that could otherwise be used to show possession of the claimed compositions. In addition, no generally accepted method for producing these unknown compositions has been set forth. It is well settled that claiming only a result (e.g., matrix materials having the ability to imprint all target molecules) fails to satisfy the constitutional requisite of promoting the progress of science and the useful arts since this seeks to monopolize all possible ways to achieve a given result (e.g., a single acrylamide matrix imprinted with an LKKATNE template peptide), far beyond those means actually discovered or contemplated by the inventor, so that others would have no incentive thereafter to explore a field already fully dominated. *O'Reilly v. Morse*, 15 How. 62, *In re Fuetterer*, 50 CCPA 1453, 1963 C.D. 620, 795 O.G.

783, 319 F.2d 259, 138 USPQ 217 ; *Siegel v. Watson*, 105 U.S. Appl. D.C. 344, 1959 C.D. 107, 742 O.G 863, 267 F.2d 621, 121 USPQ 119.

17. Claims 1-8, 11-25 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polyacrylamide surface imprint of a cytochrome c peptide, does not reasonably provide enablement for a composition created from any material that can imprint any target. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". Some of these factors may include, but are not limited to:

(1) the breadth of the claims;
(2) the nature of the invention;
(3) the state of the prior art;
(4) the level of one of ordinary skill;
(5) the level of predictability in the art;
(6) the amount of direction provided by the inventor;
(7) the existence of working examples; and
(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: Applicants' claims are directed to a broad genus of surface imprint compositions comprising a matrix material defining imprint cavities of a template molecule wherein a substantial fraction of the

imprint cavities are localized near the surface of the matrix (e.g., see claims 1 and 27). Thus, Applicants' claims encompass virtually an infinite number of compositions because no structural limitations are set forth for the matrix material, cavity or template (e.g., see specification, section 5.4, "Virtually any type of macromolecule can be captured, isolated, detected, analyzed and/or quantified using the methods and compositions of the invention"; see also 35 U.S.C. 112, second paragraph rejection (denoted c) below wherein the metes and bound of the claimed template molecules cannot be determined). That is, the specification and claims do not place any limit on the number of atoms, the types of atoms, or the manner in which said atoms might be connected to form claimed composition. Furthermore, the dependent claims likewise fail to limit one or more of these claimed elements. For example, dependent claim 2 fails to limit the target and the cavity and still reads on virtually an infinite number of polymer matrices. Consequently, the nature of the invention cannot be fully determined because the invention has not been defined with particularity.

(3 and 5) The state of the prior art and the level of predictability in the art: The level of predictability in the art is low or absent. For example, Cormack et al. state, "much more research is also required to extend the size range of templates that can be routinely imprinted. At present only small molecules ... can be imprinted with any great confidence" (e.g., see Cormack et al., "Molecular imprinting: recent developments and the road ahead" Reactive & Functional Polymers 41, 1999, 115-124, especially page 122, column 2, paragraph 3) (3/13/06 IDS, C1). Furthermore, Cormack et al. state, "a much better understanding of the imprinting process at the molecular level is necessary ... [to

develop] new functional monomers, cross-linkers and polymerization procedures" (e.g., see Cormack et al., page 122, column 1, paragraphs 1 and 2; see also Conclusions). In addition, although Cormack et al. state that the field is rapidly developing, they acknowledge that commercial products based on imprinting do not yet exist (e.g., see Cormack et al., page 123, column 1, paragraph 1), which indicates that the field is young and still developing as opposed to a more mature art.

(4) The level of one of ordinary skill: The level of skill required would be high, most likely at the Ph.D. level.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants disclose only one working example of a polyacrylamide composition that is used to define cavities for a cytochrome c protein target (e.g., see Examples 1 and 4 wherein the LKKATNE of the c-terminus is used to prepare the imprint; see also Examples 2, 3, 5, and 6 outlying various methods of use for this system). Although the specification sets forth a laundry list of other species (e.g., see claim 3 disclosing a laundry list or polymer materials), there is no evidence that any of these materials was actually made or tested.

(8) The quantity of experimentation needed to make or use the invention base on the content of the disclosure: As a result of the broad and unpredictable nature of the invention and the lack of specific guidance from the specification, the Examiner contends that the quantity of experimentation needed to make and or use the invention would be great. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as

broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 * n.23 (Fed. Cir. 19991). In this case, Applicants have not provided enough examples and/or species to teach this large, unpredictable genus. Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-3, 6-8, 11-18, 20-22 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnold et al (U.S. Patent No. 5,310,648) (Date of Patent is **May 10, 1994**).

For ***claim 1***, Arnold et al. (see entire document) disclose methods for using molecular imprint compositions that selectively bind predetermined molecules or biological particles (see Arnold et al, abstract), which anticipates the claimed invention. For example, Arnold et al. disclose a surface imprint composition comprising a matrix material defining imprint cavities of a template molecule wherein a substantial fraction of the imprint cavities are localized at or near the surface of the matrix material (e.g., see

figure 1 showing a schematic diagram for preparing a molecular imprint of a protein by metal-chelating polymers wherein said protein interacts with the exposed surface of the polymer; see also figure 3a-c showing an imprinted matrix containing chelated copper attached to a lipid monomers after matrix has been polymerized to form a rigid structure and the template molecule has been removed; see also columns 7 and 8, especially column 8, lines 11-18, "The resulting fluid imprinted matrices have a large surface area accessible for protein binding [i.e., a substantial fraction are localized at the surface] and can be used, for example, in chromatographic separations, in drug delivery, and for biosensors"; see also Examples 8-12; see especially Example 12, "Preparation of Fluid Imprinted Matrices"; see also 35 U.S.C. 112, second paragraph).

For ***claim 2***, Arnold et al. disclose polymers (e.g., see Example V, "Preparation of Imprinted Polymers"; see also Examples I and II).

For ***claim 3***, Arnold et al. disclose, for example, styrene (e.g., see Examples I and II, see also column 4, line 23; see also column 8, line 5; see also column 12, lines 40-41 wherein ethylene glycol dimethacrylate is disclosed; see also column 8, line 5 wherein methacrylate is disclosed).

For ***claims 6-8***, Arnold et al. disclose a template molecule corresponding to a portion of a macromolecule of interest such as a surface histidine residue of a protein that is bound via a metal-ligand complex (e.g., see column 6, last paragraph; see especially columns 11 and 12, Example 5 wherein the imidazole ring "portion" of a protein amino acid side chain is disclosed; see also column 4, last full paragraph for a list of various template molecules). In addition, Arnold et al. disclose that the macromolecule can be

bound at the imprint cavity (e.g., see figure 2). In addition, Arnold et al. disclose the use of the "terminal portion" of the amino acid side chains of the macromolecule such as the histidine imidazole ring (e.g., see figure 2). Furthermore, peptides containing histidine residues in the terminal portion of the chain would be immediately envisioned in view of the fact that histidine residues can occur anywhere in a peptide/protein and Arnold et al. disclose the use of all such peptides and proteins for this purpose. When, to arrive at the claimed subject matter, it is necessary to select portions of that subject matter from various sections of the reference disclosure and combine them (e.g., selecting values for variable substituents to interpolate into a generic structural formula to arrive at a specific compound or genus) anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A 17 USPQ2d 1716 (Bd. Pat. App. & Inter 1990); MPEP § 2131. Accordingly, a generic chemical formula will anticipate a species covered by the formula when the species can be "at once envisaged" from the formula. *In re Petering* 133 USPQ 275 (CCPA 1962); MPEP § 2131. See also 35 U.S.C. 112, second paragraph rejection for determining the metes and bounds of the term "corresponds" in claim 6.

For ***claims 11-16***, Arnold et al. disclose the use of peptides and proteins of all shapes and sizes (e.g., see column 4, last full paragraph, "The template molecule can be ... amino acids ... larger molecules such as peptides ... proteins"). Consequently, use of peptides of various lengths and or the terminus of said peptides would be "immediately envisioned" in accordance with MPEP § 2131. When, to arrive at the claimed subject matter, it is necessary to select portions of that subject matter from various sections of the

reference disclosure and combine them (e.g., selecting values for variable substituents to interpolate into a generic structural formula to arrive at a specific compound or genus) anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A 17 USPQ2d 1716 (Bd. Pat. App. & Inter 1990); MPEP § 2131. Accordingly, a generic chemical formula will anticipate a species covered by the formula when the species can be "at once envisaged" from the formula. *In re Petering* 133 USPQ 275 (CCPA 1962); MPEP § 2131.

For ***claims 17, 18, 20-22***, Arnold et al. disclose the use of two different template molecules to define two different cavities (e.g., see column 12 wherein the use of compounds 1 and 2 are disclosed; see more generally Example V and tables cited therein).

For ***claim 27***, Arnold et al. do not explicitly state that the cavities are "oriented", but the examiner contends that this would be an inherently disclosed by the reference because the use of polymerizable bi-layer, for example, would restrict the dimensions of the cavities accordingly (e.g., see figure 3; see also Example XII).

19. Claims 1, 2, 4, 6-8 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhao et al. (Zhao et al. "Soft lithographic methods for nano-fabrication" *J. Mater. Chem.* **1997**, *7(7)*, 1-69-1074).

For ***claim 1***, Zhao et al. disclose compositions for use in microcontact printing (e.g., see abstract; see also figure 1), which anticipates the claimed invention. For example, Zhao et al. disclose a surface imprint composition (e.g., see page 1070, figure 1,

top illustration wherein the composition represents the photoresist and Si substrate). In addition, Zhao et al. disclose that said surface imprint composition comprises a matrix material defining imprint cavities of a template molecule (e.g., see figure 1, second diagram from top wherein photoresist matrix material defines imprint cavities for the PDMS template polymer). In addition, a substantial fraction of the imprint cavities are localized at or near the surface of the matrix material (e.g., see figure 1 showing, top trace showing "all" of the cavities located at the top of the surface).

For ***claim 2 and 4***, Zhao et al. disclose photoresist polymers (e.g., see figure 1; see also page 1069, column 1, paragraph 2; see also 35 U.S.C. 112, second paragraph rejections above).

For ***claims 6-8***, Zhao et al. disclose a template molecule that corresponds to a portion of a macromolecule of interest (e.g., see figure 1, wherein the template corresponds to the terminal portions of the PDMS polymer that extend into the cavities).

For ***claim 27***, Zhao et al. disclose "oriented" cavities (e.g., see figure 1 wherein the cavities are all perpendicularly oriented with the surface; see also specification, page 12, paragraph 1 wherein the term "oriented" is defined as having a "...a similar or identical spatial relationship to the surface of the matrix material").

20. Claims 1-8, 20, 23-25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sobieszek (Sobieszek, A. "Gradient polyacrylamide gel electrophoresis in presence of sodium dodecyl sulfate: A practical approach to muscle contractile regulatory proteins" *Electrophoresis* **1994**, *15*, 1014-10-20).

For ***claim 1***, Sobieszek discloses large and small gels (e.g., see abstract; see also sections 2.2-2.6), which anticipates the claimed invention. For example, Sobieszek discloses a surface imprint composition comprising a matrix material defining imprint cavities of a template molecule (e.g., see section 2.3-2.5). In this scenario, the acrylamide or polyacrylamide represents the matrix material that defines an imprint cavity from the template "comb" (i.e., defines the loading space at the top of each lane) and is made out of Teflon (e.g., see page 1015, column 1, section 2.3). Furthermore, the cavities (i.e., the wells at the top of each lane of the gel as defined by the comb) are located at the surface of the matrix material (i.e., the top of each lane).

For ***claims 2-5***, Sobieszek discloses acrylamide polymer including a heat sensitive hydrogel polyacrylamide (e.g., see abstract; see also sections 2.3-2.6).

For ***claim 6***, Sobieszek discloses a macromolecule of interest such as Teflon i.e., polytetrafluoroethylene (e.g., see section 2.3).

For ***claim 7***, Sobieszek discloses a comb, which is bond via non-covalent interactions at the imprint cavity (e.g., see sections 2.3-2.6).

For ***claim 8***, Sobieszek discloses binding to the terminal portions of the comb that extend into the wells of the matrix (e.g., see sections 2.3-2.6).

For ***claims 20 and 23-25***, Sobieszek discloses a plurality of surface imprint compositions according to claim 1 (e.g., see sections 2.3 to 2.6 wherein both large and mini-gels are disclosed; see especially figure 3 wherein 28 minigels are simultaneously cast in a one/two dimensional array).

For ***claim 27***, Sobieszek discloses chambers that are oriented in a perpendicular

direction with respect to the top of the gel (e.g., see sections 2.3-2.6; see also figures).

21. Claims 1-8, 11-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan et al (U.S. Patent No. 5,587,273) (Date of Patent is **December 24, 1996**) as evidenced by Wikipedia (The Free Encyclopedia. Vancomycin. Retrieved at http://en.wikipedia.org/wiki/Vancomycin on June 21, 2006, pages 1-5) and Ostash et al. (Ostash et al. "Bacterial transglycosylase inhibitors" *Current Opinion in Chemical Biology* **2005**, *9*, 459-466).

For ***claim 1***, Yan et al (see entire document) disclose methods of using molecular imprint arrays on silicon wafers for use as biosensors (e.g., see Yan et al, abstract; see also column 1, lines 39-45 and column 2, lines 56-62), which anticipates the claimed invention. For example, Yan et al. disclose a surface imprint composition comprising a matrix material defining imprint cavities of a template molecule (e.g., see figure 6a). In addition, Yan et al. disclose a composition wherein a substantial fraction of the imprint cavities are localized at or near the surface of the matrix material (e.g., see figure 6a, see especially column 13, last paragraph, "To form a device which can be used to detect analytes by changes in capacitance, an imprinted polymer is spincoated onto the electrode arrangement for forming the capacitor dielectric, as indicated schematically in FIG. 6a. This allows the chemistry for introducing or removing the imprint molecules to be practiced on the exposed surface of the polymer").

For ***claims 2 and 3***, Yan et al. disclose the use of a polymer including polystyrene (e.g., see figure 6a; see also (e.g., see Yan et al., column 3, line 51).

For ***claims 4 and 5***, Yan et al. disclose heat sensitive compounds like hydrogels

and moldable plastics including polyethylene, nylon, polypropylene, polyvinyl chloride, polystyrene, acrylonitrile (e.g., see column 6, line 31; see also column 3, line 51; see also column 8, line 9).

For ***claim 6***, Yan et al. disclose a template molecule that "corresponds" to a portion of a macromolecule of interest (e.g., see Table 2). For example, various therapeutics in table 2 "correspond" to the portions of the macromolecules of interest that they bind to (e.g., see Wikipedia, the Free Encyclopedia. Vancomycin. Retrieved at http://en.wikipedia.org/wiki/Vancomycin on June 21, 2006, pages 1-5, especially, page 2, "Mechanism of Action" section showing that vancomycin corresponds to the "terminal" D-alanyl-D-alanine moieties of the NAM/NAG peptides; see also 35 U.S.C. 112, second paragraph rejection above denoted "C"). Please note that MPEP § 2131.01 allows for the use of multiple references in a 35 U.S.C. § 102 rejection in order to establish that a characteristic not disclosed by a reference is inherent.

For ***claim 7***, Yan et al. disclose that the imprint molecule can be bound to the imprint cavity (e.g., see figure 3; see also column 5, lines 28 and 53).

For ***claim 8, 11-16 and 18***, Yan et al. disclose that the template molecule corresponds to the "terminal" portion of a macromolecule such as vancomycin (see Table 2), which corresponds to the terminal portion of NAM/NAG peptides (e.g., Wikipedia, the Free Encyclopedia. Vancomycin. Retrieved at http://en.wikipedia.org/wiki/Vancomycin on June 21, 2006, pages 1-5, especially, page 2, "Mechanism of Action" section showing that vancomycin corresponds to the "terminal" D-alanyl-D-alanine moieties of the NAM/NAG peptides; see also Bohdan et al., page

460, figure 1 showing that Vancomycin binds to the D-ala-D-Ala-L-Lys-D-Glu-L-Ala peptapeptide).

For ***claims 17***, Yan et al. disclose the use of matrix materials that define at least two different template molecules (e.g., see Table 2; see also column 10, section D, see especially, column 14, paragraph 3, "A sensor for detecting multiple analytes can thus be made using the imprinted films described above. The sensor most likely would be constructed using films having recognition sites for plural analytes. For instance, a polymeric film could be formed having recognition sites for a variety of analytes, such as, without limitation, those listed in Tables 2 and 3").

For ***claims 19-25***, Yan et al. disclose the use of a spatially identifiable array including unique two dimensional arrays (e.g., see Example 3; see also figures 4-6).

Non-Statutory Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 1-8, 11-25 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-17 of U.S. Patent No.

6,979,573 (referred to herein as '573) in view of Yan et al. (U.S. Patent No. 5,587,273) (Date of Patent is **December 24, 1996**). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examiner patent claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1986).

For ***claim 1***, the '573 patent claims an imprint composition comprising a matrix material defining imprint cavities of a template molecule (e.g., see '573 patent, claims 1 and 16).

For ***claims 2 and 3***, the '573 patent claims a polymer including, for example, polymerized styrene (e.g., see '573 patent, claims 2 and 3).

For ***claims 4 and 5***, the '573 patent claims a heat sensitive compound including, for example, hydrogels (e.g., see '573 patent, claims 4 and 5).

For ***claim 6***, the '573 patent claims a template molecule that corresponds to a portion of a macromolecule of interest (e.g., see '573 patent claim 1).

For ***claim 7***, the '573 patent claims a macromolecule that is bound at an imprint cavity (e.g., see '573 patent, claim 15).

For ***claim 8***, the '573 patent claims the template molecule corresponds to a terminal portion of the macromolecule (e.g., see '573 patent, claim 6).

For ***claim 11***, the '573 patent claims the sequence of the peptide corresponds to a contiguous sequence of the polypeptide (e.g., see '573 patent, claim 10).

For ***claim 12***, the '573 patent claims the peptide is between 3 and 15 amino acids in length (e.g., see '573 patent, claim 13).

For ***claim 13***, the '573 patent claims the peptide is between 4 and 15 amino acids in length (e.g., see '573 patent, claim 13).

For ***claim 14***, the '573 patent claims the peptide is between 4 and 7 amino acids in length (e.g., see '573 patent, claim 13).

For ***claim 15***, the '573 patent claims the portion of the polypeptide comprises the C terminus of the polypeptide (e.g., see '573 patent, claim 14).

For ***claim 16***, the '573 patent claims the matrix material defines imprint cavities of at least two different template molecules (e.g., see '573 patent, claim 16).

For ***claim 17***, the '573 patent claims at least one of the template molecules corresponds to a portion of a macromolecule (e.g., see '573 patent, claim 17).

For ***claim 18***, the '573 patent claims cavities are arranged in a spatially identifiable array (e.g., see '573 patent, claim 19).

For ***claim 20***, the '573 patent claims a plurality of surface imprint compositions according to claim 1 (e.g., see '573 patent, claim 22).

For ***claim 21***, the '573 patent claims a plurality of surface imprint compositions that are unique (e.g., see '573 patent, claim 23).

For ***claim 22***, the '573 patent claims each surface imprint composition comprises a plurality of different cavities (e.g., see '573 patent, claim 24).

For ***claim 23***, the '573 patent claims a plurality of surface imprints which are arranged in a spatially identifiable array (e.g., see '573 patent, claims 24-26).

For ***claim 24***, the '573 patent claims an array which is one dimensional (e.g., see '573 patent, claim 28).

For ***claim 25***, the '573 patent claims an array which is two dimensional (e.g., see '573 patent, claim 29).

The '573 patent differs from the claimed invention as follows:

For ***claim 1***, the '573 patent fails to claim a "surface" imprint composition wherein a substantial fraction of the imprint cavities are localized at or near the surface of the matrix material.

For ***claim 27***, the '573 patent fails to claim as substantial fraction of "oriented" cavities.

However, Yan teach the following limitations that are deficient in '573:

For ***claims 1 and 27***, Yan (see entire documents) teach the use of "surface" imprint compositions wherein a substantial fraction of the imprint cavities are localized at or near the surface of the matrix material (e.g., see abstract; see also figures and examples; see especially column 13, last paragraph, "To form a device which can be used to detect analytes by changes in capacitance, an imprinted polymer is spincoated onto the electrode arrangement for forming the capacitor dielectric, as indicated schematically in FIG. 6a. This allows the chemistry for introducing or removing the imprint molecules to be practiced on the exposed surface of the polymer"). In addition, the imprint layers disclosed by Yan would inherently disclose this property because the imprint matrix is only between 5-100 nm thick and, as a result, the cavities would necessarily have to be located at or "near" the surface of the matrix (e.g., see figure 6a).

It would have been *prima facie* obvious to one skilled in the art at the time the invention was made to make a biosensor as taught by Yan et al. using the surface imprint composition as taught by '573 because Yan explicitly states that molecular imprinted materials can be used (e.g., see Yan, Field of Invention), which would encompass the molecularly imprinted materials disclosed by '573. Furthermore, one of ordinary skill in the art would have been motivated to use the molecular imprinted materials in '573 because Yan et al. explicitly state that "polymeric" materials represent a "preferred" embodiment (e.g., see Yan, Field of Invention), which would encompass the polymeric materials disclosed by '573 (e.g., see '573, claims 2 and 3). Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because both references disclose the use of polystyrene as the matrix material (e.g., see Yan et al., column 3, line 51; see also '573, claim 3). In addition, both applications disclose the use of

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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